

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:	) ) Confirmation No.: 4498 ) ) Group Art Unit: 3739
Robert J. Garabedian, et al.	
Serial No.: 10/606,250	) <b>Examiner:</b> Peffley, Michael F
Filed: June 24, 2003	)
For: Compound Lesion Alignment Device	) )

**Mail Stop Appeal Brief-Patents** 

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

#### TRANSMITTAL

Dear Sir:

Transmitted herewith is a Reply Brief (6 pages) for the above-identified application.

The Commissioner is authorized to charge Deposit Account No. 50-1105 for filing fees required for the filing of this paper.

Respectfully submitted

Dated: June 13, 2006 Michael J. Bólan

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#### CERTIFICATE OF MAILING

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Patent

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Device

# **REPLY BRIEF-CFR 41.43**

#### MAIL STOP APPEAL BRIEF-PATENTS

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

This Brief is in reply to the Examiner's Answer dated April 13, 2006. Appellant agrees with the statements made in item numbers (1)-(8) of the Examiner's Answer, and respond to the statements made in item numbers (9) and (10) of the Examiner's Answer as follows:

Appellant respectfully disagrees with the Examiner's reasoning for sustaining the rejection of claims 23-27, 29, 33-39, 44, 48, 49, and 70-81 as being obvious in view of the combination of Cosman, and to the extent that Morris is combined with Cosman, disagrees with the Examiner's reasoning for sustaining the rejection of the remaining claims 28 and 40-43.

# 1) Claims 35-38, 44, 48, 49, 72, 73, and 81

As already made clear during this proceeding, Appellant does not dispute that it is known to create compound lesions using serially or sequentially activated probes, as set forth in the background of the specification, and that it is known to create a single, large lesion using a plurality of needle electrodes guided through a stereotactic guide, as taught in Cosman. The defect in this Examiner's entire analysis, however, is that the Examiner combines these teachings without identifying in the prior art where a suggestion to make this combination can be found.

# The MPEP provides:

Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. "The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art." MPEP §2143.01(I)(emphasis added).

The MPEP further provides that in determining whether such suggestion or motivation exists in the prior art, the Examiner cannot benefit from impermissible hindsight vision afforded by the claimed invention. In particular:

Knowledge of applicant's disclosure must be put aside in reaching this determination, yet kept in mind in order to determine the "differences," conduct the search and evaluate the "subject matter as a whole" of the invention. The tendency to resort to "hindsight" based upon applicant's disclosure is often difficult to avoid due to the very nature of the examination process. However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art. (M.P.E.P. §2142) (emphasis added).

The Examiner has not gone through the analysis required by the MPEP to sustain an obviousness rejection. Rather, the Examiner has merely concluded that because it is known to sequentially or serially activate probes to provide compound lesions, then it would have been obvious to modify the Cosman method in this manner. However, the only source of any suggestion or motivation to use the Cosman guide for the purpose of guiding and sequentially activating probes to create compound lesions, is Appellant's detailed description, which the Examiner is forbidden to use in rejecting the claims, but has apparently used to make the connection between the non-guided compound lesion prior art and the guided single lesion generation method of Cosman.

When subtracting out Appellant's specification from the obviousness analysis, the only prior art that the Examiner can rely on is the fact that it is known to generate compound lesions using sequentially activated and unguided ablation probes, and Cosman, which not only fails to suggest that a stereotactic guide can be used to guide sequentially activated ablation probes for the purpose of generating compound lesions, but actually teaches against it, as discussed in detail in the Appeal Brief. The Examiner attempts to downplay Cosman's contrary teaching, stating that Cosman's adamant teaching that the creation of a single, larger lesion with a plurality of simultaneously actuated probes yields a superior result does not mitigate the fact that it is known to create a larger lesion through the use of serially or sequentially activated probe. This statement misses Appellant's point, however, which is that Cosman teaches away from using the disclosed stereotactic guide to create compound lesions—not that it is not known to create compound lesions at all.

# 2) Claims 23-26, 29, 33, 34, and 78

With respect to claim 23, the Examiner again merely concludes, without pointing to any suggestion or motivation in the prior art, that it would have been obvious to modify the Cosman method so that a single probe is inserted through different apertures of the stereotactic guide to generate compound lesions. As evidenced by the title of the patent, however, the entire disclosure of Cosman is dedicated to the concept of providing a single lesion with a cluster of electrodes, which is quite opposite to providing compound lesions with a single ablation probe, as required by claim 23. If the Cosman device and method were modified in the manner proposed by the Examiner, not only would the principle of the operation of Cosman be modified, the objective of Cosman would be defeated. It is an established principle that if a proposed modification would render the prior art device or method being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. (See M.P.E.P. §2143.01).

## 3) Claims 70, 71, 74, and 75

The Examiner opines that Appellant's statement that Cosman specifically teaches away from the use of a cannula to deliver multiple electrodes is taken out of context. Appellant disagrees. Appellant has pointed to various passages in Cosman that clearly state that a cannula with multiple electrodes is undesirable. It is difficult to imagine how all of these passages could be taken out of context.

In supporting this position, the Examiner points to the Fig. 7 embodiment to show that Cosman discloses the use of a cannula with multiple electrodes. However, Fig. 7 does not disclose a cannula—but rather a housing or carrier for the electrodes that is

not inserted through the tissue of the patient. In any event, however characterized, the housing or carrier is not disclosed as being guided through apertures of a guide to place the electrodes adjacent different regions of targeted tissue, as required by the claims.

### 4) Claims 76, 77, 79, and 80

The Examiner states that Cosman discloses that the device can be used to treat tumors in any organ on a human body, and that the skin of a human body is an organ. Based on this, the Examiner concludes that it would have been obvious to secure the Cosman device to the skin to prevent movement during the procedure. To get to this result, however, the Examiner makes many conclusions that are not supported by Cosman when read as a whole. In particular, although it is true that the skin can technically be considered an organ, it is clear that Cosman considered an organ in the traditional sense of the word—i.e., an internal organ. Otherwise, Cosman would have disclosed that the needles of the device could be percutaneously introduced through the skin into the tissue. But instead, every organ that is disclosed in Cosman as being treated by the device is illustrated and described as having a three-dimensional volume, which excludes two-dimensional skin.

Notwithstanding the foregoing, there is simply no suggestion to affix the stereotactic guide of Cosman to the skin, and the Examiner points to nothing in Cosman or any other prior art reference to suggest that one of ordinary skill in the art would affix an ablation probe guide directly to the skin of a patient. Only after reading Appellant's specification would one of ordinary skill in the art be motivated to affix the guide to the patient's skin. The Examiner merely states that it would be an intuitive and obvious consideration to one of ordinary skill in the art to modify the Cosman device

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and method in this manner. Surely more than this is required to provide a prima facie case of obviousness.

# 5) Claims 28 and 40-43

Because there is no suggestion in the prior art to modify the Cosman device and method, such that ablation probes are guided through the guide device and sequentially or serially activated to produce compound lesions, and because Morris does not supplement this failed teaching, Appellant submits that claims 28 and 40-43 are patentable.

For the above reasons, Appellant believes that the Examiner's rejections of claims 23-29, 33-44, 48, 49, and 70-81 should be overturned.

Respectfully submitted,

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Dated: June 13, 2006

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